TRIAD GROUP

June 9, 2010

Brian D. Garthwaite, PhD
Compliance Officer
Minneapolis District
Food and Drug Administration
250 Marquette Ave, Ste 600
Minneapolis, MN 55401

Dear Dr. Garthwaite,

This is our initial response to the Form 483 – Inspectional Observations issued to our firm on May 18, 2010. As agreed with the Investigators during our close-out meeting, the intent of this letter is to provide commitments to specific actions and timelines for their implementation within 15 days of the close-out discussions. Objective evidence of these actions will be provided upon their completion. For convenience, I will repeat the Observations and provide our responses immediately thereafter.

OBSERVATION 1: A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically, the firm could not provide documentation for the validation of the sterilization process for lubricating jelly products labeled as sterile.

Additionally, evidence indicates the currently used (b) (4) sterilization cycle may not be adequate to sterilize the lubricating jelly. The current sterilization cycle specifies acceptance of material that receives between a minimum of (b) (4) a maximum of (b) (4)

Triad Group Response: As described for the investigators, Triad Group is revalidating the (b) (4) sterilization processes for all sterile products according to (b) (4). In keeping with a commitment made to the Agency following our previous inspection (July, 2009), this revalidation effort will be completed by June 15, 2010. Triad Group will provide copies of the validation protocols and reports covering all Triad Group sterile products for your information shortly after that date.

Product released prior to completion of this revalidation has been released based upon (b) (4) (b) (4) testing which consistently demonstrated sterilization at sublethal doses in relation to the specified sterilization exposure.

OBSERVATION 2: Procedures for finished device acceptance have not been adequately developed.

Specifically:

- **Finished device acceptance procedures do not ensure that finished devices are quarantined or otherwise adequately controlled until acceptance criteria are met. Sterile Lubricating Jelly, lot 9M172 was packaged for (b) (4) customers. The finished product testing for customers (b) (4) passed and product was distributed. The finished product testing for customer (b) (4) failed Post Sterile Viscosity, but product was still distributed starting 01/11/10. A statement to the batch record on 01/28/10 by the Regulatory Affairs Manager states "*released by D. Haertle on 01/28/10." (D. Haertle is the CEO of H&P). On 02/10/10 an OOS was initiated to address the failed results. On 02/04/10, the decision to release the product per D. Haertle as revised per reconsideration. The remaining (b) (4) cases were scrapped. However (b) (4) cases had already been distributed and no action was taken on the distributed cases.**

- **There is no procedure addressing the "confirmatory testing" currently being implemented during microbiological testing. Currently, Sterile Lubricating Jelly is being tested for (b) (4) (b) (4) post-sterilization. The specification is listed as no growth for both tests. Since September of 2009, ten lots have shown growth on the initial test as described in Observation #1. In each case, a second sample was checked and found negative for growth. The passing results were reported and the failed results were not addressed. No OOS Investigation was initiated to investigate the failing results.**

- **The post-sterilization testing of Sterile Lubricating Jelly for (b) (4) does not neutralize the preservatives in the product. WI-LAB-0011 revision F – testing for Microbiological Contamination in Samples, effective 12/21/09 has not been updated to include the (b) (4) (b) (4) during the post sterilization testing fro lubricating jelly. On-going CAPA H-10-001 initiated 01/22/09 states in the follow-up, "(b) (4) (b) (4) (b) (4)"**

Triad Group Response:

- Triad Group will objectively review the finished product specifications for post-sterilization viscosity for Sterile Lubricating Jelly to assure that specifications are pertinent to establishing the quality, safety, and efficacy of the product. Specifications which (b) (4) (b) (4) Levels which will trigger management review prior to Lot release. Triad Group will complete this review and report our decisions by August 13, 2010. Upon completion of this review and action, no Lots of Sterile Lubricating Jelly with failing results will be released.
- The Procedure for microbiological testing will be reviewed and revised to assure that any confirmatory testing implemented following initial test failures will comply with the requirements of the *United States Pharmacopeia*. This review and revision will be completed by August 27, 2010 and a copy of the revised Procedure will be provided to you.
- Procedure WI-LAB-0011 – Testing for Microbial Contamination in Samples will be revised to include the appropriate steps for preservative neutralization. This revision will be completed by August 27, 2010; a copy of the revised procedure will be provided to you.

OBSERVATION 3

Complaints involving the possible failure of a device and labeling to meet any of its specifications were not evaluated and investigated where necessary.

Specifically, but not limited to:

- **Complaint ID 12007/Call ID 8851, dated 08/27/09 concerning Sterile Lubricating Jelly 4 oz. tube, lot 9F131, states, "***Product is sub standard. When the doctors use it, it runs right off their gloves and onto the floor. It is too runny.***" During the investigation, H&P tested (b)(4) pre-sterilization retains and (b)(4) post sterilization retains for viscosity. These samples were all produced from the same batch of product, but were packaged for different customers. All (b) (4) pre-sterilization retains failed viscosity and (b) (4) post-sterilization samples failed. The only sample that passed was packaged for the customer that made the complaint. After reporting the one passing result to the complainant, the complaint was closed without investigating the affect of the failed results on product currently on the market. H&P has received 11 viscosity related complaints from July 2009 to present.**

  Complaint ID 13100/Call ID 9688, dated 03/11/10 concerning Sterile Lubricating Jelly, 4 oz. tube, lot 9L186, states high rate of abnormal paps. Hospital lab confirms that the jelly was to blame. H&P has gotten 6 similar complaints regarding this issue from July 2009 to present.

Triad Group Response:

- In keeping with our commitment in response to Observation 2, we will assure that the post-sterilization specification is appropriate for this product (b) (4) As discussed with the Investigators, viscosity is a characteristic of this product which is influenced by user perception and preference. Triad Group receives occasional complaints that Lots of Sterile Lubricating Jelly meeting the current post-sterilization specification for viscosity are "too thick." There are also occasional complaints such as that recorded in Observation 3. Triad Group will review our Procedure for investigating customer complaints to assure that every complaint is investigated and recorded properly.
- As discussed with the Investigators, the manufacturer of the kits used in obtaining Pap smears specifically states in their labeling that no lubricant should be used in conjunction with the procedure because any lubricant has the potential to interfere with the test. Occasionally, medical facilities or practices fail to comply with this instruction and submit a complaint related to our product. Triad Group provides a copy of the manufacturer's labeling in the cases. We respectfully disagree that failure to comply with another device's labeling resulting in abnormal results represents a legitimate complaint regarding the quality, safety, or efficacy of Triad Group Sterile Lubricating Jelly.

OBSERVATION 4

A baseline report on FDA Form 3417 or approved electronic equivalent was not submitted following the first MDR report on a device model.

Specifically, the firm failed to report an adverse event related to complaint ID 13012 dated 2/17/2010 alleging over 30 patients having contracted vaginal irritation after a physician used the sterile lubricating jelly. The complaint alleged that patients were switched to a different lubrication jelly product and treated with a prescribed medication. The complainant alleged that some patients cleared of symptoms within nine days and the remaining patients exhibited symptoms for about three weeks and beyond.

Triad Group Response: Following are the details on the receipt, investigation, and disposition of this complaint:

On 3/4/2010, Triad Group initiated a review of the batch record, lot history and complaint files in response to this complaint. The batch [9B121B] was prepared without issue and met quality assurance test specifications. The batch was released at pH = (b) (4) at a viscosity post sterilization of (b) (4) cps (centipoises). A review of finished product code 19-8919, lot 9B121 certificate of processing for (b) (4) sterilization shows sterilization met the specified dosage requirements. A review of in-process batch release pre-sterilization showed a pH of (b) (4) and a viscosity of (b) (4) cps. A copy of both pre- and post sterilization batch release testing were forwarded to the complainant. A review of the in-process and finished good inspections for product code 19-8919, lot 9B121 were also within acceptable quality levels. A review of the complaint files found no other related complaints for product code 19-8919, lot 9B121 and no related trends for the product code 19-8919 or related codes over the past 12 months. An initial response was forwarded to the complaint on 3/4/2010 summarizing the investigation as detailed above.

Lab Analysis: On 3/4/2010, (b) (4) samples from the complainant were received. The tamper evident seals were in place on nine of the (b) (4) samples. These nine samples were submitted to the QA laboratory for analytical testing. The analytical testing consisted of the following: (b) (4) (b) (4) The samples provided of product code 19-8919, lot 9B121 were found to meet all Quality Assurance Laboratory analytical specifications for the product. Representative samples were tested for (b) (4) The results of these test all met specifications. In addition, the samples showed no growth after (b) (4) hours of incubation for (b) (4) Additional microbial testing was performed for the presence of (b) (4) . These test results also showed no growth. On 3/15/2010, a response outlining the analytical test results were forwarded to the complainant.

This investigation justified closing this complaint. The complainant did not provide any information which suggested a serious adverse event (death, life-threatening, hospitalization (initial or prolonged), disability, congenital anomaly or required intervention to prevent permanent impairment or damage) had occurred. The complainant did indicate that most of the patients recovered uneventfully and that only some of patients still had some minor irritation as of 2/9/2010. Upon reply to the complainant, Triad Group closed the complaint but informed the complainant it would be re-opened should further information become available at a later date – or if additional similar events were reported.

OBSERVATION 5

Written MDR procedures have not been developed and implemented.

Specifically, the firm has no MDR procedures.

Triad Group Response: A Procedure for Medical Device Reports will be written and implemented with appropriate personnel training by August 27, 2010. A copy of this Procedure will be provided for your review.

OBSERVATION 6

Corrective and preventive action activities and/or results have not been adequately documented.

Specifically, CAPA H-10-001 opened Jan 22, 2010, has yet to address high microbial bioburden levels in pre-sterile lubricating jelly products. Procedure 01-013, revision B - Corrective and Preventive Action Procedure (CAPA) which states in section 5.6 "*** (b) (4)

(b) (4)

(b) (4) ***** has not been followed.**

Triad Group Response: The entire Quality Unit will be retrained on the Triad Group CAPA Procedure and the training will be documented. This activity will be completed by June 25, 2010. Evidence of this retraining will be provided to you.

OBSERVATION 7

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

Specifically, there is no validation of the (b) (4) sterilization process for the Alcohol Swabstick products labeled as sterile.

Triad Group Response: Validation of the (b) (4) sterilization of Alcohol Swabstick Products will be completed by June 15, 2010. The validation will be conducted in accordance with (b) (4) (b) (4). Copies of the validation protocol and report will be provided to you.

OBSERVATION 8

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically, the validation for the sterilization of alcohol pads VAL-0007-PQRPT-002, approved on 3/12/10 states the minimum sterilization dose to sterilize alcohol pad products to a SAL of (b) (4) would be (b) (4). Your current specifications for your contract sterilizer, updated 4/14/10, specify you will accept product that receives a minimum dosage of (b) (4). A minimum dosage specification of (b) (4) is what you have used for the product you currently have on the market.

Triad Group response: The (b) (4) Dose Specification Authorization for Triad Group's contract (b) (4) sterilization facility has been revised to specify a minimum specified dose of (b) (4) for all Triad Group sterile alcohol swab products. Product released prior to completion of this revision has been released based upon quarterly dose audits which consistently demonstrated sterilization at sublethal doses in relation to the specified sterilization exposure.

OBSERVATION 9

Written production and process control procedures are not followed in the execution of production and process control functions.

Several examples of failure to follow Procedures related to Laboratory OOS Investigations, Corrective and Preventive Action Procedures, and General Rejection Procedures are provided.

Triad Group Response: Triad Group implemented a broad program to improve and increase the frequency of training in cGMP for all Triad Group employees in January, 2010. As part of this augmented training program, every employee with responsibilities related to the three deficiencies cited above will be retrained in each of the subject Procedures. This retraining will be completed by August 20, 2010 and objective evidence of this retraining will be provided to you.

OBSERVATION 10

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

- **No documentation exists to support that the methods used in stability testing are stability indicating.**

During the tour on 4/19/10 and 4/20/10, several activities were observed that were not controlled by procedures:

- **Repacking of product was taking place in the warehouse in an unsegregated area.**
- **Rechecking of material on the packaging lines when defects are noted during the finish product inspection are not documented or controlled by a procedure.**
- **"Hold" stickers are being used by Quality during an OOS investigation.**
- **"Return to Inventory" tags.**
- **Receiving material under quarantine from the New Jersey plant prior to all testing being completed.**

Triad Group Response:

- The Triad Group Quality Assurance Laboratory is undertaking a review of all stability test methods to assure that the methods are, in fact, stability indicating. This review will include, but is not limited to, (b) (4) products in the samples. Given the extent of this review, we target completion and implementation of revised methods by October 1 2010. We will provided regular status reports on this program at bimonthly intervals and will include copies of the revised methods for your information.
- Effective immediately, all packaging or repackaging operations will be conducted in appropriate manufacturing suites. These operations will be subject to current, approved line clearance Procedures and will require in-process and finished product inspection and release by Triad Group Quality Control inspectors.
- We will review the existing Procedures for finished product inspection to assure that rechecking of material on the packaging lines when defects are noted, or increased sampling and inspection, is controlled by an appropriate Procedure and correctly documented. This review will be completed by June 30, 2010 and we will provide a copy of the corresponding document and evidence of training on its use to you.
- We will write and implement a Procedure to adequately control use of "Return to Inventory" tags, and train appropriate personnel in its proper use. This will be completed by June 25, 2010 and a copy of the Procedure with objective evidence of effective training will be provided to you.
- We will write and implement a Procedure to adequately control receipt of material under quarantine from our New Jersey facility, and train appropriate personnel in its proper use. This will be completed by June 25, 2010 and a copy of the Procedure with objective evidence of effective training will be provided to you.

OBSERVATION 11

Drug products failing to meet established specifications are not rejected.

Specifically:

- **Triad Plus BZK Prep Pads have a BZK, wt% specification of (b) (4) Batches of this product were released outside of this specification range as follows:**

Date	Lot Number	Finished Product Results	Quantity	Released Under Deviation
08/26/09	9H104	(b) (4)	(b) (4) cases	NO DEV/OOS WRITTEN
02/01/10	0A38/0A38B		(b) (4) cases	(b) (4)

- **Hemorrhoid Cream has a phenylephrine specification of 0.225 - 0.275%. Batches of this product were released outside of this specification range as follows:**

Date	Lot Number	Finished Product Results	Quantity	Released Under Deviation
11/05/09	9J140B/9J140	(b) (4)	(b) (4) gallons	(b) (4)
09/18/09	9K213/9K213B		(b) (4) cases	

Triad Group Response: There are open Corrective and Preventive Action (CAPA) processes for both of these issues. We are actively investigating the interactions of (b) (4) (b) (4) formulations. Our CAPA activities are not limited to these two focuses, however. We anticipate having effective and appropriate resolutions to these issues by fourth-quarter of this year; we will provide bimonthly progress reports on our actions to close these CAPAs to you.

In the future, drug products failing to meet established specifications will be rejected in all cases unless an adequate and appropriate justification for release by deviation, including a review of potential for effect on quality, safety, or efficacy of the product, is established and documented.

OBSERVATION 12

Results of stability testing are not used in determining expiration dates.

Specifically, numerous OTC batches involving various products failed during the annual stability studies. Data obtained during stability testing is not used to determine if expiration dates need to be adjusted.

Formula	Lot	Mo. Failed	Exp. Date	Formula	Lot	Mo. Failed	Exp. Date
10-5102	9A135	(b) (4)	01/12	04-112	8F133	(b) (4)	06/10
04-132	8J123		09/11	04-193	7E68		05/10
04-148	8J144		09/11	04-158	7D04		04/10
04-098	8E53	(b) (4)	05/11	04-132	7K63	(b) (4)	10/09
04-201	7H05		08/10	04-084	7G22		07/09
04-136	8G172		07/10				

Triad Group Response: As we discussed with the Investigators during the inspection close-out, we have implemented an in-depth review of our entire stability test program. This review will include (b) (4) Each of these events will be reviewed and the potential for effect on the assigned expiration date for the product will be considered. This investigation will include (b) (4) (b) (4) Expiration dating will be adjusted when appropriate as a result of this investigation. We

anticipate being able to complete this program by October 29, 2010. We will provide bimonthly status reports on this program and specify any expiration dating periods which require revision.

OBSERVATION 13

Investigations of a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product.

Specifically,

- **Numerous OTC batches involving various products failed during the annual stability studies. No investigation was documented determining the affect of these failures to product currently on the market as listed in Obervation 12.**
- **The firm identified (b) (4) suppositories in the following batches of infant and adult glycerin suppositories:**

Triad Group Response:

- Please refer to our response to Observation 12, above. As stated, our stability program optimization review will include consideration of the potential effect of documented failures. Should we identify any circumstances with potential to adversely affect the quality, safety, or efficacy of a distributed lot we will recall that lot and promptly advise you of that action.
- The history of the lots of glycerin suppositories listed in Observation 13 was exhaustively discussed with the Investigators over the course of the inspection. The only outstanding issue at the conclusion of the inspection was the status of Lot 0D118, labeled and shipped to (b) (4). While there was no evidence that this Lot was contaminated, we could not provide absolute assurance that it was not. Consequently, Triad Group recalled Lot 0D118 by telephone call and overnight-delivered letter to (b) (4) recall coordinator. Minneapolis District Recall Coordinator Kristy Zarowski.

OBSERVATION 14

Written procedures are not drafted, reviewed and approved by the appropriate organizational units.

Procedure WI-LAB-0123, revision A - Analytical Method Validation and Verification states in 3.1, "(b) (4) (b) (4) ." During the review of various validation methods, it was observed that the validation protocols were not signed off prior to the execution of the validation.

Protocol	Effective Date	Execution Date
VAL-P-0092	12/08/09	12/01/09
VAL-P-0171	02/04/10	12/30/09
VAL-P-0011	12/23/09	07/06/09
VAL-P-0084	12/08/09	11/17/09

Triad Group Response: Validation and Quality Unit personnel will be retrained on the provisions of Procedure WI-LAB-0123. This retraining will be completed by June 25, 2010 and objective evidence will be provided to you.

OBSERVATION 15

Deviations from written specifications are not justified.

Specifically:

- **Deviation Form 01-019, rev. C, attachment II states in the corrective action section, "(b) (4) (b) (4) (b) (4) " No corrective actions/justifications were written for deviations H0210.001 dated 02/01/10 and H1109.007 dated 11/5/09.**

- **Deviation P0207.008 dated 02/16/07 concerning towelettes states, "*** (b) (4) (b) (4) (b) (4) *** CAPA H-10-002 concerning the failing (b) (4) in finished goods and stability samples was not issued until 02/02/10.**

Triad Group response: Quality Unit personnel will be retrained on the appropriate implementation of Deviation Requests and Corrective and Preventive Actions. Specific emphasis will be provided on these two Observations. We will complete this training by June 25, 2010; documentation of this training will be provided to you.

OBSERVATION 16

Employees engaged in the manufacture and packing of a drug product lack the training required to perform their assigned functions.

Specifically,

Temporary employees do not receive formal training before they operate production lines.

- **On 04/19/10, during the packaging of product PL-5104B, Lot OD143, on line CB4, temporary employee (b) (6) (b) (6) was documenting the Top Seal Temperature at (b) (4) for the (b) (4) checks taken (b) (4) The specification for the top seal is (b) (4) F.**

- **On 04/19/10, during the packaging of product 11-SP03, Lot OD15, on line HB5, temporary employee (b) (6) (b) (6) documented the Top Seal Temperature at (b) (4) The specification for the top seal is (b) (4) (b) (4) °F. The top seal temperature was observed running at (b) (4) °F during our observation of line HB5 at ~3:30pm on 04/19/10.**

Training did not appear adequate for the regular employees due to the numerous documentation errors noted throughout this inspection. These include, but are not limited to:

- **On 04/13/10, batch OD153B, the incorrect lot number was documented and verified by a second employee for the Cocoa Butter NF. This error was not caught until an investigator noted it during the inspection on 04/21/10.**
- **On 01/26/10, for specification 04-132, step (b) (4) the step was performed by (b) (6) but was never verified.**
- **The batch records state do not run outside of process parameters, however multiple instances were documented where production lines were being run outside of operating parameters.**

Triad Group Response:

- Triad Group will review the cGMP training that is provided for temporary employees with particular emphasis on those employees with responsibility for controlling processes or recording process parameters to assure that this training is adequate and effective. We will provide a report of this activity to you by July 30, 2010.
- Please refer to comments on augmented cGMP training in response to Observation 9, above. The first training session on cGMP requirements for documentation was conducted on June 4, 2010. A record of that training is enclosed for your review. Ongoing training and reports on that training were described in the response to Observation 9, above.
- Triad Group (b) (4) with specific training and experience in internal compliance audits and cGMP training. (b) (4) effective June 16, 2010.

OBSERVATION 17

Reprocessing was performed without the review of the quality control unit.

Specifically, the Infant and/or Adult Glycerin Suppositories, formula 04-144, are manufactured using (b) (4) (b) (4) **are 'approved' by Quality, no specification for** (b) (4) **or documented criteria for what Quality is looking for could be provided.**

Triad Group Response: While we believe that our current procedure as described in the Master Batch Record for glycerin suppository products is adequate to address this issue, Triad Group will revise the Master Batch Record to include appropriate specifications (b) (4) and to document Operations and Quality Control approval. This document will be issued and appropriate training on its use will be conducted by July 16, 2010. We will provide a copy of this revised Master Batch Record and objective evidence of training on it to you.

OBSERVATION 18

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically, some OTC drug products are currently being released for distribution prior to the completion of all release testing.

- **One batch can be used to package several packaging configurations. Testing is required at the (b) (4) each packaging run. (b) (4) (b) (4)**

(b) (4)

testing is required.

Sample	Testing Required
(b) (4)	(b) (4)

Batch	Product	Samples Tested	Date Released	# Cases
OB166	(b) (4) Glycerin Suppositories	(b) (4)	03/05/10	(b) (4)
OB166	(b) (4) Glycerin Suppositories		03/04/10	
OB166	(b) (4) Glycerin Suppositories		03/15/10	

Assay testing was approved by Quality for (b) (4) Glycerin Suppositories for (b) (4) sample on 03/09/10 (b) (4) (b) (4) Glycerin Suppositories were released before Assay testing (b) (4) sample.

Testing was completed for (b) (4) sample on 08/17/10 for BZK product 9H104. (b) (4) testing was completed on 08/26/10 with failing results for BZK, (b) (4) Assay. The first pallet containing (b) (4) cases was released into inventory for shipping on 08/14/09. The second pallet containing (b) (4) cases was released into inventory for shipping on 08/19/09. Product was shipped as follows:

Dated	#Cases
08/14/09	(b) (4)
08/19/09	(total)

No investigation occurred when failed results were documented for the End Sample for product already in inventory. The remaining cases were released into inventory and shipped.

Triad Group response: The Triad Group Procedure for finished product inspection, testing and release will be reviewed for adequacy and compliance with the requirements of cGMP. This review will address the cited examples of release of finished products prior to completion of all release testing and appropriate investigation and corrective action for any incidence of failed results for product already in inventory. We will have this significant review and revision activity completed by September 10, 2010 and we will provide you with a report of this activity accompanied by revised Procedures and objective evidence of training on the revised Procedures.

OBSERVATION 19

The written stability testing program is not followed.

Procedure WI-LAB-0063, revision C - Stability Study Program states in section 3.4.1, "**(b) (4) (b) (4) (b) (4) **** Numerous test points were missed during the execution of stability protocols with no deviations being written.**

Solution #	Lot #	Missed time point(s)
04-011B	9A135	(b) (4)
04-132	8J123	
04-148	8J144	
04-098	8E53	
04-201	7H05	
04-136	8G172	

Solution #	Lot #	Missed time point(s)
04-112	8F133	(b) (4)
04-193	7E68	
04-158	7D04	
04-132	7K63	
04-084	7G22	

Triad Group Response: Please refer to our response to Observation 10, above. Triad Group is confident that completion of this program within the time commitment provided is adequate to address this Observation.

OBSERVATION 20

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically, no raw data could be provided to support the Cleaning Validation Report for the Glycerin Suppository Press dated 12/29/09.

Triad Group Response: While we believe that cleaning validation Val-CV-GSM-002 for glycerin suppository press is adequate to address this issue, we acknowledge that summary results rather than raw data were recorded in the final report. Triad Group will (b) (4) executed cleaning validation protocol. This portion of the Procedure will be re-executed and finalized by no later than July 30, 2010 and a copy of the amended Report will be provided to you.

OBSERVATION 21

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically,

- The Infant and Adult Glycerin Suppository filling line is not appropriate for the manufacture of the OTC drug products in that there were cracked ejector pins on the glycerin press. The production work order for Specification 07-SOL-04-144IN, batch OB166B states in section IX, "***Check the Glycerin Press for broken pins; if any broken pins are observed, alert Production Supervisor.***" There is no additional information documented as to what steps were taken to correct the problem or whether the production supervisor was contacted and if so, if any follow up occurred.
- The foam punches used to cut the pads used in drug and cosmetic products manufactured by the firm are not easily cleanable and were patched with tape.
- The tank used to manufacture the oatmeal products had holes in the bottom that were patched using tape. This tape has contact with product.

Triad Group Response:

- As discussed with the Investigators, we believe that this was a misunderstanding of the configuration and routine appearance of the (b) (4) pins on the glycerin suppository press. Additionally, we have received no complaints of broken pin fragments in suppositories. However, we will retrain the glycerin suppository press operators on the Production Work Order Specification 07-SOL-04-1441N to assure that they are aware of the appearance of intact pins as well as potential appearance of broken pins, and that they will notify their supervisor if they observe this problem. We will complete this retraining by June 25, 2010 and we will provide objective evidence of this retraining to you.
- As discussed with the Investigators at close-out, the pads produced on the subject press are subject to inspection prior to release from our facility and are further subjected to incoming inspection by customers purchasing these component pads. Triad group will review potential improvement to this process and will provide you with a summary report of our investigations and conclusions.
- As discussed with the Investigators at close-out, the oatmeal bath product is not actually "manufactured." Bulk oatmeal is emptied from bulk paper bags and filled into individual foil pouches. No formulation or processing is performed other than this filling operation. Given that the product is not sterile and is stored and received in paper bags Triad Group does not believe that the patching observed by the Investigators has potential to contaminate or effect the quality of the product. However, we will review potential improvements in this process and we will provide a summary of our review and any actions taken to you.

OBSERVATION 22

Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

- The fans used in the Swab room to dry the swabs were observed on 04/19/10 to have accumulation of debris.
- The wire baskets used in the Swab room to hold the swabs while they are drying were observed to have frayed wires and an accumulation of grey fuzz.
- The plastic scraper used in the manufacturing of the oatmeal products was chipped. The wooden handle was broken and taped together and was not easily cleanable.

Triad Group Response:

- The nature of the swab forming process results in release of cotton fibers into the room. Triad Group has implemented improved cleaning procedures for this room to better address this issue. A copy of this Procedure is enclosed for your review. We would like to note that the room was thoroughly cleaned immediately following this Observation and the Investigators were asked to tour the cleaned room. There was no mention of this effective cleaning in the Inpectional Observations.
- The wire baskets were all inspected and either repaired or removed from service immediately following this observation
- The makeshift utensil described was removed from the oatmeal production room immediately. No inappropriate utensils will be allowed in the oatmeal production room or any production area in the facility.
- Each of these Observations was addressed with corrective actions during the course of the subject inspection and the Investigators were provided copies of the cleaning procedure for the swab forming area. There have no complaints or quality issues that would suggest product problems related to any of these Observations.

OBSERVATION 23

Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

- **Procedure WI-PM-0056, revision B - Cleaning and Sanitizing Batching Equipment, Tanks and Totes states the following:**

  Page 5: **Glycerin Suppositories/Clean and Sanitize Between Batches. Section 7 states, "***(b) (4) (b) (4) ***. The Lab Manager stated this process is currently (b) (4) (b) (4) as shown by the log for tank 61.**

  Page 4: Ointment and Suppository Products/ (b) (4) (b) (4) . The log for tank 44 and 42 shows batch information not being documented and cleanings not being performed (b) (4) batches.

- **Procedure WI-PM-0113, original - Performing Daily Calibration on (b) (4) Suppository Machine Scales states in section 3.1.14, "(b) (4) (b) (4) ." Lot OB132 dated 02/12/10 documents the scale reading at (b) (4) % for all (b) (4) scales.**

- **Procedure WI-PM-0090, original - Assigning Status Tags to Batch Tanks states the following:**

  Section 3.1.2, "(b) (4) ." **Although tank 44 was in use, no batch information was recorded for tank 44 for the following dates: 3/19/10, 3/23/10, 3/24/10,** 3/25/10, **3/29/10, 3/31/10, 4/09/10, 4/12/10, 4/19/10.**

Triad Group Response: Please refer to our response to Observation 9, above. Triad Group is confident that completion of this augmented ongoing training will effectively prevent recurrence of the errors identified.

In closing, we would like to offer two additional comments, with due respect, on the focus and conduct of this inspection. First – over the three-week course of this inspection the Investigators requested, and were provided at Triad Group expense, copies of many hundreds of pages of documents. These copies were selectively chosen to document potential errors or omissions and so did not document the overwhelming majority of reviewed documents which were completed entirely correctly. Similarly – the Notice of Observations Form FDA 483 contains only negative observations selectively presented. Even corrections made in the Investigators' presence were not noted. Triad Group is concerned that this selective presentation of problems out of context demonstrates a lack of balance in the approach to inspection and has the potential to portray a false impression of our compliance status. These concerns were presented to the Investigators during the close-out discussions.

Triad Group appreciates this opportunity to respond to the inspectional observations; we look forward to continued dialogue with the District.

Yours truly,

Jack Waterman

John H. Waterman
Manager, Regulatory Affairs